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No. 97-1095

In The

Supreme Court of the United States

October Term, 1997

BECTON DICKINSON VASCULAR ACCESS, INC.,

Petitioner,

v.

CRITIKON, INC.,

Respondent.

On Petition For A Writ Of Certiorari To The United States Court Of Appeals For The Federal Circuit

BRIEF IN OPPOSITION

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RULE 29.6 STATEMENT

In accordance with Supreme Court Rule 29.6, Respondent refers to page ii of Petitioner's Brief.

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Respondent adopts the abbreviations used by petitioner in its Petition for a Writ of Certiorari.

STATEMENT OF THE CASE

The petitioner's statement of the case is inaccurate, incomplete, and misleading. Consequently, respondent Critikon, Inc. provides the following complete statement of the case.

A. Background

Over the years, the use of intravenous catheters has become widespread, particularly in hospitals and healthcare facilities where they facilitate the introduction of medicinal fluids into patients. The principal difficulty in using an intravenous catheter is that it requires the use of a sharp steel introducer needle. (21a-22a). The use of a sharp needle creates a high risk of accidental needlesticks and the associated risk of infection, especially in the healthcare industry. (Id.). Due to the increased risk of exposure to AIDS during the 1980's, there was a tremendous need for a safety catheter that would protect healthcare workers from accidental needlesticks and the associated risk of infection with bloodborne pathogens. (Id.).

Respondent and petitioner have long competed against one another in the manufacture and sale of conventional (*i.e.*, non-safety) catheters. Respondent is the leader in inventing, developing and marketing improved safety catheters. Respondent's own efforts resulted in the issuance of the Lemieux and Dombrowski patents, both of which are directed towards important new safety catheter inventions that markedly decrease the transmission of bloodborne pathogens in healthcare facilities throughout the world. As a result of respondent's research and

development, respondent was the first to market its patented ProtectIV® line of safety catheters that have saved scores of lives over the years.

In contrast to respondent, petitioner performs little if any of its own research and development. Rather, petitioner focuses its efforts on marketing knock-off medical devices. Indeed, in the few instances where the petitioner has attempted its own research and development of safety catheters, the Federal Circuit correctly held those attempts to be abysmal failures. (13a-15a).

B. The Patents In Suit

Both the Lemieux and Dombrowski patents are directed to new safety catheters that aid in the prevention of accidental needlesticks. (3a). While the safety catheters disclosed in the two patents differ significantly in the way they operate, both automatically position a needle guard over the tip of a needle to protect the healthcare worker from accidental needlesticks. (3a). In the case of the Lemieux patent, the disclosed preferred embodiment describes a safety catheter where a notch or discontinuity on the needle secures the needle guard in a position to protect the healthcare worker from an accidental needlestick. (24a). The Dombrowski patent discloses a preferred embodiment using a tether to retain the needle guard over the tip of the needle, as an alternative to using a notch on the needle as disclosed in Lemieux. (47a).

At trial, the parties stipulated that the Lemieux patent was "prior art" to the Dombrowski patent. (46a). Thus, by stipulation, the parties agreed that the technique of using a notch on a needle – as disclosed in Lemieux for

securing the needle guard over the needle tip – was known to persons skilled in the art before Dombrowski. Indeed, the petitioner unequivocally asserted in its opening brief to the Federal Circuit "that a person of ordinary skill in the art . . . would have been motivated . . . to lock the needle guard to a discontinuity in the needle." In so arguing, the petitioner further contended in the Federal Circuit that this very approach was disclosed in the "Vanderhoof patent,"[1] another patent predating Dombrowski. In its reply brief in the Federal Circuit, petitioner again stated that the use of a notch on a needle was "the approach used in the Vanderhoof patent where a slidable needle guard is positioned . . . and secured to a groove in the needle."

At trial, the petitioner's expert witness, Mr. Fischell admitted that the Dombrowski safety catheter did not require the use of a tether:

> Q: Now, in fact, the cap in Dombrowski could be prevented from falling off without a long tether like this if you used the engaging means similar to Mr. Lemieux; correct?
>
> A: Yes.

In sum, the evidence was undisputed that (i) Dombrowski does not require the use of a tether, and (ii) that one of ordinary skill in the art would have known that a notch could have been used instead of a tether in the Dombrowski safety catheter.

---

[1] Petitioner told the Federal Circuit that the "Vanderhoof patent . . . describes . . . a needle guard that locks into a slot . . . to secure the guard over the needle tip."

With the foregoing admitted facts, petitioner's contention that the Dombrowski patent is invalid under 35 U.S.C. §112 collapses. Consequently, by the overwhelming evidence and the admissions of petitioner, the district court was correct in concluding that "one of ordinary skill in the art" would have known that a notch could be used with the Dombrowski safety catheter in lieu of a tether. (47a-48a).

C. The Petitioner Freely Copied the Lemieux and Dombrowski Inventions

The petitioner's second question presented implies that the district court made findings of fact supporting petitioner's contention that its infringing product was independently developed. Independent development, however, never occurred. Contrary to petitioner's attorney argument, the district court specifically held that the evidence showed that the petitioner was certainly "less cautious than it ordinarily might have been in assessing its position vis-à-vis a competitor's [*i.e.*, respondent's] recently issued patents." (42a). Moreover, the district court specifically found that there was clear and unmistakable evidence of petitioner's "imprudence." (42a). Plainly, the district court believed that the facts pointed towards copying, not towards independent development.

The Federal Circuit agreed. As the Federal Circuit held, the evidence was "overwhelming" that prior to obtaining copies of the Lemieux and Dombrowski patents, petitioner's efforts to independently develop a safety catheter were an abject "failure." (14a-15a). The evidence showed that petitioner formally launched its

project to design and market a safety catheter in January 1989. By April 1990, petitioner focused on one particular design that, at that time, petitioner thought was quite promising. But, as the Federal Circuit correctly held, petitioner's proposed design "proved dangerous and commercially unacceptable." (14a).

Petitioner's internal memorandum summarizes the collapse of its attempt at independent development:

> There is no doubt that the results [of petitioner's safety catheter trials] are extremely negative. Making it even more disappointing is the fact that we don't even know what some of the negative comments meant - e.g., difficulty inserting could have been due to any number of things - lubrication, shield drag against skin, whippy needles, etc. From the study we have no sense of [sic] at all of precisely what was going wrong.
>
> * * *
>
> Lots of problems. Some anticipated and identified for study, others mysterious and still undefined/quantified/qualified.

In addition to having created a thoroughly worthless design, petitioner's engineers "could not precisely identify the problems associated with their device." (14a). Petitioner's engineers simply had "no sense . . . at all of precisely what was going wrong."

Critikon's growing success with its ProtectIV® safety catheter in the marketplace alarmed petitioner's president, Dr. Vincent DeCaprio. Petitioner's management was growing impatient and could wait no longer for results.

Dr. DeCaprio decided to act. He told the petitioner's engineers to abandon their unsuccessful efforts to develop an independent design and move "fast" to "hit J&J's [*i.e.*, respondent's] ProtectIV® design." Petitioner's engineers looked for a quick solution.

By early 1991, petitioner had obtained copies of the Lemieux and Dombrowski patents, and had studied the patents thoroughly. Based on Dr. DeCaprio's directive, petitioner abandoned its failed attempt to independently develop a safety catheter. Rather, petitioner turned to the slavish copying of Critikon's patents. As the Federal Circuit held, petitioner specifically copied key features disclosed in the Lemieux and Dombrowski patents. (15a). The facts conclusively show, as the Federal Circuit correctly held, that petitioner "managed to commercialize its design by adopting features disclosed in the Dombrowski patent and the Lemieux patents soon after it became aware of their existence." (15a). In the end, the infringing Saf-T-Cath® safety catheter introduced by the petitioners was little more than a knock-off of respondent's patents.

In sum, petitioner's contention that its infringing safety catheter design was the result of independent development is pure fabrication.

D. Petitioner Acted with "Utter Disregard for the Need to Obtain Competent Legal Advice"

In 1991, petitioner began making a large number of infringing Saf-T-Cath® safety catheters. Petitioner contends that the facts show that, in embarking on these infringing activities, its management proceeded in good

faith based on competent opinions of counsel. (Petitioner's Brief at 5). The facts show just the opposite.

Petitioner's own internal memoranda show that petitioner's management knew full well that its Saf-T-Cath® was "patent infringing." Even petitioner's senior patent counsel, Mr. Rodrick, warned petitioner's senior management about the risk of infringing respondent's patents. Indeed, all of petitioner's top management was involved in the decision to willfully infringe respondent's patents, including petitioner's in-house counsel (Mr. Rodrick), and petitioner's top executive, Dr. DeCaprio.

In the district court and in the Federal Circuit, petitioner relied on eight purported "opinions" from patent counsel in an attempt to show good faith. (13a). This attempt to show good faith, as the Federal Circuit held, was a sham. Only four of the so-called "opinions" were prepared before the onset of the infringing activity. (13a-14a). The Federal Circuit summarily rejected petitioner's reliance on the later four opinions, and petitioner has abandoned reliance on those opinions. (13a-14a).

As for the earlier four opinions, the Federal Circuit correctly rejected petitioner's good faith argument. The Federal Circuit correctly held that the opinions did not even address the actual infringing commercial Saf-T-Cath® at issue in the litigation. (14a). Petitioner does not dispute that fact. Moreover, as the Federal Circuit held, the opinions were "superficial and conclusory in nature." (14a). There was "no analysis of specific claims, no interpretation of claim language . . . and no meaningful discussion of the prosecution history." (14a). In sum, the evidence clearly showed, and the Federal Circuit

correctly held, that petitioner's management and attorneys "demonstrated utter disregard for the need to obtain competent legal advice" before embarking on the infringing activities. (15a).

SUMMARY OF THE ARGUMENT

Petitioner seeks review of three questions, none of which even approach justifying the request for a grant of a writ of certiorari. In the first instance, none of the questions are presented on the facts of this case. Moreover, no error of law or conflict with any decision of this Court or any other court has been demonstrated; rather, both lower courts correctly cited and followed all pertinent authorities.

1. Petitioner's first question is not presented on the facts of the case. According to the petitioner, the Dombrowski patent is invalid because its specification does not enable one of ordinary skill in the art to make and use the claimed invention. On the contrary, the undisputed facts show that one of ordinary skill in the art would without question know how to practice the inventions claimed in the Dombrowski patent. This conclusion is supported by undisputed evidence adduced at trial, including the parties' stipulation and the admission of the petitioner's own witness. Moreover, the decision of both lower courts are fully in accord with the controlling authorities.

2. Petitioner's second question is also not presented on the facts. Contrary to petitioner's argument, after

hearing the testimony of petitioner's claimed independent development story, the district court found that the petitioner was "less cautious than it" should have been "in assessing its positions vis-à-vis . . . [respondent's] recently issued patents." (42a). Moreover, the district court specifically held that there were clear "signs of . . . [petitioner's] imprudence." (42a). Under well-settled controlling authorities, the Federal Circuit was correct in finding petitioner guilty of copying the Lemieux and Dombrowski patents.

3. Petitioner's third question is, again, not presented on the facts of this case. The Federal Circuit was plainly correct in finding that the opinions of counsel relied on by petitioner to excuse its infringing conduct were simply not competent. Moreover, the Federal Circuit again carefully followed the controlling authorities, correctly stated the applicable law, and correctly applied the law to the facts.

REASONS FOR DENYING THE WRIT

The three questions presented by the petitioner are not presented on the facts of this case. Moreover, the Federal Circuit correctly stated the controlling rules of law, and properly applied those rules to the facts. At best, petitioner argues that the facts found below are erroneous. This argument is wrong on the merits and, in any event, is an argument that simply does not justify review by this Court. (Sup.Ct.R. 10).

A. This Case Does Not Present any Violation of the Patent Statutes as Alleged by Petitioner

Petitioner's first question alleges that both lower courts erred in rejecting petitioner's argument that the Dombrowski patent is invalid under 35 U.S.C. §112. Petitioner is wrong on the law and wrong on the facts.

The Dombrowski patent discloses a safety catheter having a needle guard that automatically moves into position to shield the tip of the needle. (3a). The Dombrowski patent discloses that a tether, as an alternative to a notch on the needle, may be used to hold the needle guard into position over the needle tip. (47a). Petitioner argues, in essence, that asserted claims 18 and 19 of the Dombrowski patent (which do not require the use of a tether) are not supported by an enabling disclosure and are therefore invalid under 35 U.S.C. §112.

As the district court correctly held, 35 U.S.C. §112 permits the enablement requirement to be met by teachings that can be found in the prior art. (47a-48a). Petitioner does not challenge this rule of law, nor could it. Indeed, the rule was articulated over a century ago by this Court in *Mowry v. Whitney*, 81 U.S. (14 Wall.) 620, 644 (1871) and in *Webster Loom Co. v. Higgins*, 105 U.S. (15 Otto.) 580, 585 (1881). Numerous Federal Circuit cases are in accord, including *Seattle Box Co. v. Industrial Crating & Packing, Inc.*, 731 F.2d 818, 826 (Fed.Cir. 1984), cited by the district court. *See, e.g., Spectra-Physics, Inc. v. Coherent, Inc.*, 827 F.2d 1524, 1534 (Fed.Cir. 1987), *Hybritech Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1384 (Fed.Cir. 1986).

At trial, the parties stipulated that the Lemieux patent was prior art to the Dombrowski patent – meaning, of course, by petitioner's own stipulation, that the teachings of Lemieux (the use of a notch on a needle to hold the needle guard in place) would have been known to one of ordinary skill in the art. (46a). Moreover, petitioner even went so far as to affirmatively contend in the district court and the Federal Circuit that the prior art Vanderhoof patent disclosed the use of a notch on a needle. (*Supra* at §I.B). Finally, petitioner's own expert witness freely admitted at trial that the Dombrowski safety catheter simply did not require the use of a tether. (*Supra* at §I.B). These undisputed facts therefore establish that both lower courts were plainly correct in finding that the petitioner failed to prove invalidity under 35 U.S.C. §112 by clear and convincing evidence.

Petitioner gains nothing from *In re Glass*, 492 F.2d 1228 (CCPA 1974), *In re Argoudelis*, 434 F.2d 1390 (CCPA 1970), or *Engel Indus. v. Lockformer Co.*, 946 F.2d 1528 (Fed.Cir. 1991). (Petitioner's Brief at 9-10). In *Glass*, unlike here, the prior art was insufficient on the facts to supplement the disclosure of the patent in issue. 492 F.2d at 1233. *Argoudelis* and *Engel Indus.* simply state the well-settled rule of law that whether a patent meets the requirements of 35 U.S.C. §112 is measured as of the time the pertinent patent application was filed. *Argoudelis*, 434 F.2d at 1393; *Engel Indus.*, 946 F.2d at 1532. None of these cases state any rule of law that is in any way inconsistent with the decisions of the two lower courts here.

Plainly, petitioner's argument at best presents a case of an alleged misapplication of a properly stated rule of law. This Court's own rules point out that such a case

simply does not warrant review by this Court. (Sup.Ct.R. 10). Moreover, as both lower courts found, petitioner is simply wrong on the facts. Once again, at best, petitioner's contention that both lower courts made erroneous fact findings simply does not justify granting certiorari (Sup.Ct.R. 10).

B. This Case Does Not Present any Violation of Rule 52(a), Fed.R.Civ.P.

Petitioner's second question alleges that the Federal Circuit failed to follow the "clearly erroneous" standard governing appellate review of district court fact findings. Rule 52(a), Fed.R.Civ.P. Petitioner concedes that this question is one that is grounded in alleged "erroneous fact findings," (Petitioner's Brief at 12), and not on any alleged error of law. Petitioner also concedes that the Federal Circuit correctly stated the appropriate standard of review under Rule 52(a). (Petitioner's Brief at 12; 13a). For both reasons, the petitioner's second question is not one this Court should review. (Sup.Ct.R. 10).

The pertinent factual issue is whether, as the Federal Circuit held, the petitioner independently developed its infringing Saf-T-Cath® safety catheter. The facts unequivocally showed rather that petitioner freely copied respondent's patents.

In the first instance, the petitioner's attempt to find support for its conduct in the district court's opinion is makeweight. After hearing testimony at trial by the petitioner's engineers, the district court rejected the "independent development" story. (41a-42a). Petitioner's claim of independent development fell apart after Mr. Gerald

H. Peterson, petitioner's manager of research and development, admitted at trial that at the time petitioner fixed the design of its infringing Saf-T-Cath,® he was carefully studying the Lemieux and Dombrowski patents to understand why petitioner's own design efforts had been such a complete failure. The district court ultimately concluded that the petitioner was "less cautious than it ordinarily might have been in assessing its positions vis-à-vis . . . [the Lemieux and Dombrowski] patents." (42a). Moreover, the district court held that there were clear signs of petitioner's "imprudence." (42a). Thus, contrary to petitioners' contention, (Petitioner's Brief at 12), the testimony at trial showed copying, not independent development. Thus, on the facts, petitioner's attempt to create some issue under Rule 52(a), Fed.R.Civ.P., is completely baseless.

Ultimately, the district court excused petitioner's conduct on the ground that it was justified in copying respondent's patents because the safety catheter field was rapidly developing. (13a, 42a-43a). The Federal Circuit disagreed, holding that the fact that a field was rapidly developing simply does not excuse copying, a well-settled legal principle not contested by petitioner. (14a-15a). On the facts, the Federal Circuit, after reviewing the evidence that overwhelmingly pointed towards copying, correctly concluded that petitioner commercialized its infringing design by "adopting features disclosed in the Dombrowski patent and the Lemieux patents soon after it became aware of their existence." (15a).

Plainly, petitioner's second question is a poorly disguised and improper attempt to seek review of fact findings that are manifestly correct. The request for review by this Court should be denied.

C. Petitioner's Attempt to Escape a Finding of Willful Infringement is Baseless

Petitioner's third question alleges that the Federal Circuit misapplied the appropriate legal standard for determining whether petitioner was guilty of willful infringement. Petitioner agrees that the Federal Circuit properly stated the correct rule of law, (Petitioner's Brief at 13), but, according to petitioner, misapplied that law. Clearly, petitioner's third question – even assuming petitioner's erroneous statement of the facts – is one that does not warrant review by this Court. (Sup.Ct.R. 10).

On the facts, petitioner's question is premised on the assertion that petitioner possessed a competently prepared opinion of counsel justifying its infringing activity, and that the opinion was relied on in good faith by petitioner's management. Here, petitioner relies on just one opinion prepared by an outside patent attorney, Mr. A.T. Kammer. (56a-66a). For three separate reasons, Kammer's opinion is wholly useless to justify petitioner's conduct.

In the first instance, the evidence showed that Mr. Kammer's opinion was pure windowdressing. An internal memorandum prepared by the petitioner at the time it embarked on its infringing activity showed that petitioner's management knew all along that its Saf-T-Cath® design was "patent infringing." Moreover, the evidence

showed that petitioner's president (Dr. DeCaprio) and in-house patent counsel (Mr. Rodrick) were fully in support of petitioner's scheme to infringe the Lemieux and Dombrowski patents. It is telling that petitioner never brought Mr. Kammer (or Mr. Rodrick or Dr. DeCaprio) to trial in an attempt to support its attorney argument.

Secondly, as the Federal Circuit held, the Kammer opinion is entitled to no weight because it did not even "discuss the infringing catheter product," (14a), but instead discusses a catheter design wholly irrelevant to this litigation. Petitioner does not contest this fact. Rather, petitioner, agreeing *sub silentio* that the opinion is wholly worthless on the infringement issue, attempts to sidestep this fatal flaw by relying only on Mr. Kammer's conclusory assertion that the Dombrowski patent is invalid. But, the opinion states that the Dombrowski patent contains no valid claims "which cover the proposed [safety catheter] assembly." (56a). Clearly, the fact that the opinion is directed to the wrong safety catheter undermines not only its infringement analysis but also its validity analysis.

Finally, as the Federal Circuit held, the opinion is "superficial and conclusory," having no meaningful interpretation of the claim language or discussion of the prosecution history. (14a). As noted above, the only interpretation of the claims relies on the flawed approach of tying the claim language back to the wrong safety catheter. Moreover, the discussion of the prosecution history is so cursory as to be meaningless. (57a-59a). On the validity analysis, petitioner relies on a conclusory one page chart attached to the opinion as an afterthought. (66a). At trial, neither Mr. Kammer nor anyone else ever

attempted to justify the conclusory and erroneous contentions on that chart. Indeed, the evidence at trial showed that those contentions were thoroughly frivolous.

CONCLUSION

For the foregoing reasons, the petition for a writ of certiorari should be denied.

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